MAR 2 8 2014

510(k) Summary

Device Trade Name: PEEK Fusion Implant

Manufacturer:
MTP Solutions LLC
124 South 600 West, Suite 100
Logan, UT 84321

Contact:
Mr. Robert Hoy
Director of Technical & Clinical Research
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Prepared by:
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Washington, DC 20005
Phone: (202) 552-5800
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Date Prepared: March 28, 2014

Common Name: Screw, Fixation, Bone

Classification: 21 CFR 888.3040

Class: II

Product Code: HWC

Indications for Use:
The PEEK Fusion Implant is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe and mallet toe.

Device Description:
The PEEK Fusion Implant is manufactured from polyetheretherketone (PEEK) and is composed of two threaded components, each designed to engage either side of an osteotomy or reconstruction site. Once in position, the components mate with one another allowing for reduction and fixation of the bone fragments.

Predicate Devices:
The PEEK Fusion Implant is substantially equivalent to the Arthrex Bio-Pin (marketed as the Trim-It Pin) [K050259], the OsteoMed ExtremiFuse [K130412] and the Nextremity FlexFusion Implant (marketed as the Nextra) [K110445] with respect to its indications for use, geometry, dimensions, function and performance.

Technological Characteristics Comparison:
The PEEK Fusion Implant and its predicate devices are similar in size and all generally cylindrical in shape. In addition, all devices are designed to be deployed across osteotomy and reconstruction sites with the purpose of fixing bone fragments. The PEEK Fusion Implant is manufactured from polyetheretherketone (PEEK) while the Arthrex Bio-Pin predicate is composed of poly (L-lactide); the OsteoMed ExtremiFuse predicate is made from titanium alloy and the Nextremity FlexFusion predicate from stainless steel. All four materials are present in many FDA cleared permanent implants and have a long history of biocompatibility. The biocompatibility of the candidate device material is further substantiated by the data available in an FDA Master File. In addition, mechanical test results demonstrate that the difference in material increases the construct strength as determined in side-by-side testing vs. a predicate device. Therefore, this difference in technology introduces no new issues of safety or effectiveness.

Nonclinical Testing:
Pre-clinical testing has been performed for the PEEK Fusion Implant to assure substantial equivalence to a predicate device and to demonstrate the device performs as intended. All testing was performed on test units representative of finished devices. Clinical data were not needed to support the safety and effectiveness of the subject device.

The device design was qualified through the following tests:

- Tensile Strength Testing
- Bending Strength Testing
- Torsion Strength Testing
- Shear Strength Testing
- Screw Insertion Testing
- Driver Torque to Failure Testing
- Association & Disassociation Testing
- Four-point Bending Fatigue Testing
- Tensile Load after Fatigue Testing

The results of this testing demonstrate that the PEEK Fusion Implant performs as intended and has greater bending, torsion, shear and post-fatigue tensile strength and equivalent time zero tensile strength and fatigue performance when compared to the predicate. In addition, the driver/implant interface torque failure loads exceeded the torque required to insert the implants and no disassociation of the implants was observed during fatigue testing.

Conclusion:
The PEEK Fusion Implant met all specified criteria performing as intended and did not raise any new issues of safety or effectiveness. The Indications/Intended Use and the fundamental scientific technology of the PEEK Fusion Implant are similar to those described in the predicate devices. The PEEK Fusion Implant has been determined by MTP Solutions to be substantially equivalent to the Arthrex Bio-Pin (marketed as the Trim-It Pin) [K050259], the OsteoMed ExtremiFuse [K130412] and the Nextremity FlexFusion Implant (marketed as the Nextra) [K110445].

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 28, 2014

MTP Solutions LLC
Mr. Robert Hoy
Director of Technical & Clinical Research
124 South 600 West, Suite 100
Logan, Utah 84321

Re: K133515
Trade/Device Name: PEEK Fusion Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: March 4, 2014
Received: March 5, 2014

Dear Mr. Hoy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PEEK Fusion Implant – Traditional 510(k)

4. Indications for Use

510(k) Number (if known): K133515

Device Name: PEEK Fusion Implant

Indications for Use:

The PEEK Fusion Implant is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe and mallet toe.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of _____

Elizabeth L. Frank -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K133515